IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIONOGI INC. AND CONCORDIA PHARMACEUTICALS INC.,	)	
	)	C. A. No.: 16-606-LPS
Plaintiffs,	)	
v.	)	
ACTAVIS LABORATORIES UT, INC.,	)	
Defendant.	)	

DEFENDANT'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Defendant Actavis Laboratories UT, Inc. ("Actavis"), by and through its undersigned attorneys, answers the complaint of Plaintiffs Shionogi Inc. and Concordia Pharmaceuticals Inc. (together, "Plaintiffs") as follows:

RESPONSE TO "NATURE OF THE ACTION"

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Actavis's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Plaintiffs' ULESFIA® drug product prior to the expiration of United States Patent Nos. 6,793,931 ("the '931 patent") and 7,294,342 ("the '342 patent") (collectively, "the patents-in-suit").

Answer: Actavis admits that Plaintiffs purport to bring this action under the patent laws of the United States based on Actavis's filing of an ANDA with the FDA seeking approval to commercially market a generic version of ULESFIA® prior to the expiration of U.S. Patent Nos. 6,793,931 ("the '931 patent") and 7,294,342 ("the '342 patent"), but denies that the Plaintiffs' allegations have any merit.

RESPONSE TO "THE PARTIES"

2. Plaintiff Shionogi Inc. ("Shionogi") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Campus Drive Florham Park, NJ 07932.

Answer: Upon information and belief, admitted.

3. Plaintiff Concordia Pharmaceuticals Inc. ("Concordia") is a société à responsabilité limitée (limited liability company) duly continued and validly existing under the laws of the Grand-Duchy of Luxembourg, having its registered office at 8-10 Avenue de la Gare L-1610 Luxembourg, Grand-Duchy of Luxembourg, and having a Barbados Branch with a branch address at Canewood Business Centre, 5 Canewood Industrial Park, St. Michael, Barbados, BB11005.

Answer: Actavis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 and therefore denies them.

4. Upon information and belief, Defendant Actavis Laboratories UT, Inc. ("Actavis") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 577 Chipeta Way, Salt Lake City, UT 84108. Upon information and belief, Actavis manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Actavis also prepares and/or aids in the preparation and submission of Abbreviated New Drug Applications ("ANDA") to the FDA.

Answer: Actavis admits that it is a Delaware corporation having a place of business at 577 Chipeta Way, Salt Lake City, UT 84108. Actavis admits that it is engaged in the business of developing and manufacturing generic pharmaceutical products, some of which are ultimately distributed into Delaware and throughout the United States, and that Actavis submits ANDAs to the FDA.

RESPONSE TO JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

Answer: Admitted.

6. This Court has personal jurisdiction over Actavis by virtue of the fact that, inter alia, it is a Delaware corporation and has systematic contacts with the State of Delaware.

Answer: Actavis answers that it will not contest personal jurisdiction for purposes of this action only.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Answer: Actavis answers that it will not contest venue is proper in this Court for purposes of this action only.

RESPONSE TO THE PATENTS-IN-SUIT

8. On September 21, 2004, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '931 patent, entitled "Ectoparasite Asphyxiator Compositions and Methods for their Applications" to Summers Laboratories, Inc. ("Summers") as assignee of the inventor Michael J. Precopio. A copy of the '931 patent is attached hereto as Exhibit A.

Answer: Actavis admits that, on its face, the '931 patent is entitled "Ectoparasite Asphyxiator Compositions and Methods for their Applications" and the '931 patent states that it was issued on September 21, 2004 to Summers Laboratories, Inc. ("Summers") as assignee of Michael J. Precopio, whom the '931 patent states is the inventor. Actavis admits that Plaintiffs purport to have attached a copy of the '931 patent to the Complaint as Exhibit A. Actavis denies that the '931 patent was "duly and lawfully issued."

9. On November 13, 2007, the USPTO duly and lawfully issued the '342 patent, entitled "Ectoparasite Asphyxiator Compositions and Methods for their Applications" to Summers as assignee of the inventor Michael J. Precopio. A copy of the '342 patent is attached hereto as Exhibit B.

Answer: Actavis admits that, on its face, the '342 patent is entitled "Ectoparasite Asphyxiator Compositions and Methods for their Applications" and the '342 patent states that it was issued on November 13, 2007 to Summers as assignee of Michael J. Precopio, whom the '342 patent states is the inventor. Actavis admits that Plaintiffs purport to have attached a copy

of the '342 patent to the Complaint as Exhibit B. Actavis denies that the '342 patent was "duly and lawfully issued."

10. On or about December 26, 2007, Summers assigned its rights to the '931 and '342 patents to Sciele Pharma ("Sciele"). On or about September 1, 2008, Shionogi acquired Sciele, including Sciele's rights to the '931 and '342 patents. Shionogi is the current assignee of the '931 and '342 patents. On or about May 6, 2013, Shionogi exclusively licensed its rights to the '931 and '342 patents to Concordia.

Answer: Actavis lacks information or knowledge sufficient to form a belief as to the truth of the allegations in paragraph 10 of the Complaint and therefore denies the same.

RESPONSE TO THE ULESFIA® DRUG PRODUCT

11. Shionogi holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for ULESFIA® (Benzyl Alcohol) Lotion, 5%. ULESFIA® was approved for the topical treatment of head lice infestation in patients 6 months of age and older on April 9, 2009.

Answer: Actavis admits that Shionogi is the purported owner of an approved NDA for (Benzyl Alcohol) Lotion, 5%, which is sold under the trade name ULESFIA®. Actavis lacks information or knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 11 of the Complaint and therefore denies the same.

12. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to ULESFIA®. The claims of the patents-in-suit cover, inter alia, compositions and methods for treating ectoparasite infestations on animal skin and hair.

Answer: Actavis admits that the '931 patent and the '342 patent are listed in the FDA publication, "Approved Drug Products and Therapeutic Equivalence Evaluations," as covering the ULESFIA® drug product. Except as expressly admitted above, Actavis denies the allegations of paragraph 12 of the Complaint.

RESPONSE TO THE ACTS PURPORTEDLY GIVING RISE TO THIS ACTION

13. Pursuant to Section 505 of the FFDCA, Actavis filed ANDA No. 209212 ("Actavis's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation into the United States of Benzyl Alcohol Lotion, 5% ("Actavis's Proposed Product"), before the patents-in-suit expire.

Answer: Actavis admits that it submitted ANDA No. 209212 ("Actavis's ANDA") to the FDA under § 505(j) of the FFDCA, seeking approval to market a lotion containing 5% benzyl alcohol in the United States. Actavis denies the remaining allegations in paragraph 13 of the Complaint.

14. In connection with the filing of its ANDA as described in the preceding paragraph, Actavis has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Actavis's ANDA.

Answer: Actavis admits the allegations in paragraph 14 of the Complaint.

15. On or about June 2, 2016, Plaintiffs received written notice of Actavis's ANDA certification ("Actavis's Notice Letter"). Actavis's Notice Letter alleged that the claims of the '931 and '342 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Actavis's ANDA. Actavis's Notice Letter also informed Plaintiffs that Actavis seeks approval to market Actavis's Proposed Product before the '931 and '342 patents expire. In the Notice Letter, Actavis did not assert non-infringement of claims 1-2, 4-6, 8-17, 20-23, 26, 28-29 and 32-38 of the '931 patent or claims 1 and 3-16 of the '342 patent. Actavis therefore concedes that Actavis' Proposed Product would infringe those claims of the '931 and '342 patents, respectively, if used, manufactured, sold, offered for sale, or imported into the United States.

Answer: Upon information and belief, Actavis admits that Actavis's Notice Letter alleged that the claims of the '931 patent and the '342 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Actavis's ANDA, and admits further that Actavis's Notice Letter referred to Actavis's ANDA which contains a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Actavis's Proposed Product before the expiration of the '931 and '432 patents. Except as expressly admitted above, Actavis denies the allegations of paragraph 15 of the Complaint.

RESPONSE TO COUNT I: ALLEGED INFRINGEMENT OF THE '931 PATENT

16. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

Answer: Actavis repeats and incorporates by reference its responses to the preceding paragraphs as if fully set forth herein.

17. Actavis's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation into the United States of Benzyl Alcohol Lotion, 5%, prior to the expiration of the '931 patent, constituted infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Actavis admits that it submitted an ANDA seeking approval to market a lotion containing 5% benzyl alcohol in the United States. Actavis denies the remaining allegations of paragraph 17 of the Complaint.

18. There is a justiciable controversy between the parties hereto as to the infringement of the '931 patent.

Answer: Actavis admits the allegations of paragraph 18 of the Complaint.

19. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will infringe the '931 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States.

Answer: Actavis denies the allegations of paragraph 19 of the Complaint.

20. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will induce infringement of the '931 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States. On information and belief, upon FDA approval of Actavis's ANDA, Actavis will intentionally encourage acts of direct infringement with knowledge of the '931 patent and knowledge that its acts are encouraging infringement.

Answer: Actavis denies the allegations of paragraph 20 of the Complaint.

21. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will contributorily infringe the '931 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States. On information and belief, Actavis has had and continues to have knowledge

that Actavis's Proposed Product is especially adapted for a use that infringes the '931 patent and that there is no substantial noninfringing use for Actavis's Proposed Product.

Answer: Actavis denies the allegations of paragraph 21 of the Complaint.

22. Plaintiffs will be substantially and irreparably damaged and harmed if Actavis's infringement of the '931 patent is not enjoined

Answer: Actavis denies the allegations of paragraph 22 of the Complaint.

23. Plaintiffs do not have an adequate remedy at law.

Answer: Actavis denies the allegations of paragraph 23 of the Complaint.

24. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Answer: Actavis denies the allegations of paragraph 24 of the Complaint.

RESPONSE TO COUNT II: ALLEGED INFRINGEMENT OF THE '342 PATENT

25. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

Answer: Actavis repeats and incorporates by reference its responses to the preceding paragraphs as if fully set forth herein.

26. Actavis's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation into the United States of Benzyl Alcohol Lotion, 5%, prior to the expiration of the '342 patent, constituted infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Actavis admits that it submitted an ANDA seeking approval to market a lotion containing 5% benzyl alcohol in the United States. Actavis denies the remaining allegations of paragraph 26 of the Complaint.

27. There is a justiciable controversy between the parties hereto as to the infringement of the '342 patent.

Answer: Actavis admits the allegations of paragraph 27 of the Complaint.

28. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will infringe the '342 patent under 35 U.S.C. § 271(a) by making, using, offering to

sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States.

Answer: Actavis denies the allegations of paragraph 28 of the Complaint.

29. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will induce infringement of the '342 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States. On information and belief, upon FDA approval of Actavis's ANDA, Actavis will intentionally encourage acts of direct infringement with knowledge of the '342 patent and knowledge that its acts are encouraging infringement.

Answer: Actavis denies the allegations of paragraph 29 of the Complaint.

30. Unless enjoined by this Court, upon FDA approval of Actavis's ANDA, Actavis will contributorily infringe the '342 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Actavis's Proposed Product in the United States. On information and belief, Actavis has had and continues to have knowledge that Actavis's Proposed Product is especially adapted for a use that infringes the '342 patent and that there is no substantial noninfringing use for Actavis's Proposed Product.

Answer: Actavis denies the allegations of paragraph 30 of the Complaint.

31. Plaintiffs will be substantially and irreparably damaged and harmed if Actavis's infringement of the '342 patent is not enjoined.

Answer: Actavis denies the allegations of paragraph 31 of the Complaint.

32. Plaintiffs do not have an adequate remedy at law.

Answer: Actavis denies the allegations of paragraph 32 of the Complaint.

33. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Answer: Actavis denies the allegations of paragraph 33 of the Complaint.

RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

34. Actavis denies that Plaintiffs are entitled to any of the relief requested in paragraphs (A) through (I) of the "Prayer for Relief," or any relief whatsoever.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer or to its ability to seek and allege any and all additional defenses not presently known or that are revealed during the course of discovery, Actavis states the following defenses in response to the Complaint:

FIRST AFFIRMATIVE DEFENSE

Each purported claim for relief in the Complaint is barred for failure to state a claim on which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, or importation of the Actavis product that is the subject of Actavis's ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '931 patent or the '342 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

THIRD AFFIRMATIVE DEFENSE

Each and every claim of the '931 patent and the '342 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including at least 35 U.S.C. § 103.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs may not seek injunctive relief against Actavis because Plaintiffs' alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

WHEREFORE, Actavis prays that this Court:

A. Enter an order dismissing the Complaint, with prejudice, and denying Plaintiffs the relief requested in the Complaint and any relief whatsoever;

B. Deny Plaintiffs any award of damages, costs, or fees;

C. Declare this case exceptional and award Actavis its reasonable attorneys' fees;

D. Award Actavis its costs; and

E. Grant such other and further relief as this Court may deem just.

COUNTERCLAIMS

Without admitting any of the allegations of Shionogi Inc. ("Shionogi") and Concordia Pharmaceuticals, Inc. ("Concordia") (collectively, "Counterclaim Defendants"), other than those expressly admitted herein, and without prejudice to the right of Actavis Laboratories UT, Inc. ("Actavis") to plead additional Counterclaims as the facts of the matter warrant, Actavis hereby asserts the following Counterclaims against Counterclaim Defendants.

NATURE OF THE ACTION

These Counterclaims seek a declaratory judgment that the lotion containing 5% benzyl alcohol described in the ANDA that is the subject of the Complaint in this action ("ANDA No. 209212") does not infringe any valid and enforceable claim of U.S. Patent No. 6,793,931 ("the '931 patent") or U.S. Patent No. 7,294,342 ("the '342 patent") (collectively, "patents-in-suit"), and that each and every claim of the patents-in-suit is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. § 103.

THE PARTIES

1. Actavis is a Delaware corporation having a place of business at 577 Chipeta Way, Salt Lake City, UT 84108.

2. Upon information and belief, and also based on the allegations in paragraph 2 of the Complaint, Shionogi is a Delaware corporation with a principal place of business located at 300 Campus Drive, Florham Park, NJ 07932.

3. Upon information and belief based on the allegations in paragraph 3 of the Compliant, Concordia is a société à responsabilité limitée (limited liability company) duly continued and validly existing under the laws of the Grand-Duchy of Luxembourg, having its registered office at 8-10 Avenue de la Gare L-1610 Luxembourg, Grand-Duchy of Luxembourg, and having a Barbados Branch with a branch address at Canewood Business Centre, 5 Canewood Industrial Park, St. Michael, Barbados, BB11005.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that the Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court may declare the rights and other legal relations of the parties involved pursuant to 28 U.S.C. §§ 2201 and 2202, because this case is based on an actual controversy within the Court's jurisdiction seeking a declaratory judgment that Actavis has not, by the submission of ANDA No. 209212 to the FDA for a lotion containing 5% benzyl alcohol, infringed any valid claim of the patents-in-suit, and that the patents-in-suit are each invalid and/or unenforceable.

6. Personal jurisdiction over Counterclaim Defendants is proper at least because Counterclaim Defendants have availed themselves of the legal protections of the State of

Delaware by voluntarily submitting to and employing the jurisdiction of this Court in this matter and at least one other.

7. Venue for these Counterclaims is properly within this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b) because Counterclaim Defendants have voluntarily submitted to the jurisdiction of the Court in this matter.

FACTUAL BACKGROUND

8. According to the United States Food & Drug Administration ("FDA") publication entitled *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book"), Shionogi holds approved New Drug Application ("NDA") No. 022129 for a lotion containing 5% of the active ingredient benzyl alcohol, marketed under the trade name ULESFIA®.

9. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

10. Upon information and belief based on the allegations in paragraph 10 of the Complaint in this matter, Shionogi is the current owner of, and has the right to enforce, the patents-in-suit.

11. Upon information and belief based on the allegations in paragraph 10 of the Complaint in this matter, Concordia is the exclusive licensee of the patents-in-suit.

12. Upon information and belief, Shionogi caused the patents-in-suit to be listed in the Orange Book as patents that claim ULESFIA®, or methods of using ULESFIA®. ULESFIA® is a pediculocide indicated for the topical treatment of head lice infestation in patients 6 months of age and older.

13. Actavis submitted ANDA No. 209212 to the FDA, seeking approval to engage in the commercial manufacture, use or sale of a lotion containing 5% of the active ingredient benzyl alcohol prior to the expiration of the patents-in-suit.

14. ANDA No. 209212 contains Paragraph IV Certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of a lotion containing 5% of the active ingredient benzyl alcohol.

15. On or around June 1, 2016, Actavis sent Counterclaim Defendants a notice letter providing notice of Actavis's submission of ANDA No. 209212 to the FDA ("the Notice Letter"). The Notice Letter contained notifications of Actavis's Paragraph IV Certifications to the FDA that the patents-in-suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, or sale of a lotion containing 5% of the active ingredient benzyl alcohol.

16. On July 14, 2016, Counterclaim Defendants filed this lawsuit alleging that Actavis infringes the patents-in-suit.

COUNT I
(Declaratory Judgment of Invalidity of U.S. Patent No. 6,793,931)

17. Actavis realleges and incorporates by reference the allegations in paragraphs 1-16 of these Counterclaims as if fully set forth herein.

18. There is an actual, substantial, continuing, and justiciable controversy between Actavis and Counterclaim Defendants regarding the validity of the '931 patent, based on Counterclaim Defendants' allegations in their Complaint that Actavis has infringed or will infringe the '931 patent.

19. At least for the reasons explained in Actavis's Notice Letter in the section titled: "Detailed Factual and Legal Bases for Actavis' Paragraph IV Certification That The Claims Of U.S. Patents Nos. 6,793,931 and 7,294,342 Are Invalid, Unenforceable and/or Not Infringed," claims 1-38 of the '931 patent are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. § 103.

20. Actavis is entitled to a judicial declaration that claims 1-38 of the '931 patent are invalid.

COUNT II
(Declaratory Judgement of Noninfringement of U.S. Patent No. 6,793,931)

21. Actavis realleges and incorporates by reference the allegations in paragraphs 1-16 of these Counterclaims as if fully set forth herein.

22. There is an actual, substantial, continuing, and justiciable controversy between Actavis and Counterclaim Defendants regarding whether Actavis's submission of ANDA No. 209212 to the FDA and/or Actavis's manufacture, use, offer to sell, sale, and/or importation into the United States of a lotion containing 5% of the active ingredient benzyl alcohol infringes, has infringed, or will infringe any valid and enforceable claim of the '931 patent, if any, either directly or indirectly, and either literally or under the doctrine of equivalents.

23. At least for the reasons explained in Actavis's Notice Letter in the section titled: "Detailed Factual and Legal Bases for Actavis' Paragraph IV Certification That The Claims Of U.S. Patents Nos. 6,793,931 and 7,294,342 Are Invalid, Unenforceable and/or Not Infringed," Actavis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '931 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

24. Actavis is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '931 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of a lotion containing 5% of the active ingredient benzyl alcohol has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '931 patent.

COUNT III
(Declaratory Judgment of Invalidity of U.S. Patent No. 7,294,342)

25. Actavis realleges and incorporates by reference the allegations in paragraphs 1-16 of these Counterclaims as if fully set forth herein.

26. There is an actual, substantial, continuing, and justiciable controversy between Actavis and Counterclaim Defendants regarding the validity of the '342 patent, based on Counterclaim Defendants' allegations in their Complaint that Actavis has infringed or will infringe the '342 patent.

27. At least for the reasons explained in Actavis's Notice Letter in the section titled: "Detailed Factual and Legal Bases for Actavis' Paragraph IV Certification That The Claims Of U.S. Patents Nos. 6,793,931 and 7,294,342 Are Invalid, Unenforceable and/or Not Infringed," at least claims 1-16 of the '342 patent are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. § 103.

28. Actavis is entitled to a judicial declaration that at least claims 1-16 of the '342 patent are invalid.

COUNT IV
(Declaratory Judgement of Noninfringement of U.S. Patent No. 7,294,342)

29. Actavis realleges and incorporates by reference the allegations in paragraphs 1-16 of these Counterclaims as if fully set forth herein.

30. There is an actual, substantial, continuing, and justiciable controversy between Actavis and Counterclaim Defendants regarding whether Actavis's submission of ANDA No. 209212 to the FDA and/or Actavis's manufacture, use, offer to sell, sale, and/or importation into the United States of a lotion containing 5% of the active ingredient benzyl alcohol infringes, has infringed, or will infringe any valid and enforceable claim of the '342 patent, if any, either directly or indirectly, and either literally or under the doctrine of equivalents.

31. At least for the reasons explained in Actavis's Notice Letter in the section titled: "Detailed Factual and Legal Bases for Actavis' Paragraph IV Certification That The Claims Of U.S. Patents Nos. 6,793,931 and 7,294,342 Are Invalid, Unenforceable and/or Not Infringed," Actavis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '342 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

32. Actavis is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '342 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of a lotion containing 5% of the active ingredient benzyl alcohol has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '342 patent.

PRAYER FOR RELIEF

WHEREFORE, Actavis respectfully requests that this Court enter judgment against Shionogi and Concordia and issue an order:

A. Dismissing the Complaint with prejudice and denying each request for relief made by Shionogi and Concordia therein;

B. Declaring the claims of the the '931 patent and the '342 patent invalid;

C. Declaring that the filing of ANDA No. 209212 has not infringed and does not infringe any valid and enforceable claim, if any, of the'931 patent or the '342 patent, either directly or indirectly, and either literally or under the doctrine of equivalents;

D. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of a lotion containing 5% of the active ingredient benzyl alcohol does not, and would not, if marketed, infringe any valid and enforceable claim, if any, of the '931 patent or the '342 patent, either directly or indirectly, and either literally or under the doctrine of equivalents;

E. Declaring that this case is an exceptional case in favor of Actavis pursuant to 35 U.S.C. § 285;

F. Declaring Actavis the prevailing party and awarding costs and attorneys' fees to Actavis; and

G. Awarding Actavis such other and further relief as the Court deems just and equitable.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Melanie K. Sharp

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